YOGA-BASED PULMONARY REHABILITATION FOR THE MANAGEMENT OF DYSPNEA IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity, mortality, and health care use [1]. COPD-Chronic obstructive pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to the noxious particles or gases.

Objectives: To evaluate the effectiveness of Yoga Therapy in the management of dyspnea and fatigue in patients with COPD.

Materials and methods: sixty COPD(18 to 60years) were recruited. The yoga group received an yoga module for COPD that included asanas, loosening exercises, breathing practices, pranayama, meditation, yogic counseling and lectures 45 min/day, 3days/weeks on alternate days for 12 weeks. Measurements of dyspnea and fatigue on the spirometry, exercise capacity by the 6 min walk test, COPD QUESTIONAIRE, and C –Reactive protein (CRP) for inflammatory response were made before and after the intervention.

Results: Statistically significant within group reductions in dyspnea (P <0.001), COPD questionaire (P <0.001) scores, CRP (P <0.001), and 6 min walk distance (P <0.001) were observed in the yoga group; all except the last were significant compared to controls (P <0.001).

Conclusions: Findings indicate that yoga benefits patients with COPD. Yoga can now be included as an adjunct to conventional therapy for pulmonary rehabilitation to Most cases of COPD can be prevented by programs for COPD patients.

KEYWORDS: Chronic obstructive pulmonary disease, Dyspnea, Yoga

1. INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity, mortality, and health care use [1]. COPD-Chronic obstructive pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to the noxious particles or gases. Exacerabation and comorbidities contribute to the overall severity in
individual patient. COPD is a leading cause of morbidity and mortality worldwide and results in an economic and social burden that is both substantial and increasing. About 3 million die due to COPD every year. In India, median prevalence of COPD is 5% in men and 2.7% in women and about half a million people die due to reducing exposure to risk factors. This includes decreasing rates of smoking and improving indoor and outdoor air quality. While treatment can slow worsening, there is no cure. COPD treatments include stopping smoking, vaccinations, respiratory rehabilitation, and often inhaled bronchodilators and steroids. Some people may benefit from long-term oxygen therapy or lung transplantation. In those who have periods of acute worsening, increased use of medications and hospitalization may be needed.

As of 2015, COPD affects about 174.5 million (2.4%) of the global population. It typically occurs in people over the age of 40. Males and females are affected equally commonly. In 2015 it resulted in 3.2 million deaths, up from 2.4 million deaths in 1990.

Pulmonary rehabilitation is a comprehensive intervention that includes exercise training, education, and behavior modification, designed to improve the physical and psychological condition of people with COPD [10]. The evidence is increasing for the efficacy of several kinds of exercise training as part of pulmonary rehabilitation aimed at reducing dyspnea and fatigue, as well as improving health-related quality of life and exercise capacity in individuals with COPD [11]. Yoga has been included as a component of exercises prescribed for many pulmonary rehabilitation programs [12],[13]. Studies of short-term yoga practices have reported improved lung function parameters [14], increased diffusion capacity [15], decreased dyspnea-related distress [16], and improved health-related quality of life [17].

Yoga therapy program includes asanas; pranayama; relaxation techniques; meditation; yogic counseling for stress management; chanting; and lectures on yogic lifestyle and philosophy [30].

Limited studies on COPD using other yoga systems have assessed its efficacy in an adjunctive role. Here we report a randomized controlled study of COPD, evaluating the effects of yoga. We hypothesized that these parameters would improve in yoga group as compared to a control group.

2. MATERIALS AND METHODS
2.1 PARTICIPANTS

The COPD patients of Shanti Devi Charitable Trust, Ashok Vihar, Delhi, India, were recruited as study participants. The study sample consisted of 60 (male & female) patients in the age range 18 to 60 years.

INCLUSION CRITERIA
1. Age > 18 years
2. History, examination and PFT consistent with COPD as per GOLD guidelines. PFT showing:
   - FEV1/FVC < 0.70
   - Irreversible bronchial obstructions (<12% and/or <200ml increase in FEV1 or FVC, 20 minutes after the administration of 200µg of inhaled salbutamol).

EXCLUSION CRITERIA
1. History of acute respiratory tract infection in the past 4 weeks prior to study
2. History of medication with antibiotics and/or steroids (oral, injection or inhalation) in the previous 4 weeks prior to study.
3. Patients with cardiovascular disease, diabetes mellitus, Neuro-musculo-skeletal deficits, tuberculosis, hepatic or renal diseases.
4. Pregnant and lactating females.
5. History of thyroid disorders, parathyroid disorder and thyroidectomy

The baseline value of the following parameters will be measured before including the subjects into the study:
1. Pulmonary function test (PFT).
   a) Force vital capacity (FVC)
   b) Force expiratory volume in 1 second (FEV1)
   c) FEV1 / FVC%
   d) FEF 25 -75

2. High sensitive C-reactive protein (hs CRP) [mg/l]

   - All subjects will be classified as per GOLD stage i.e. patients having FEV1/FVC <0.70 and:FEV1 ≥ 80% predicted GOLD Stage 1-mild
   - 50% ≤ FEV1 < 80% predicted GOLD stage 2-moderate.
   - 30% ≤ FEV1 < 50% GOLD stage 3-severe.
   - FEV1<30% predicted GOLD stage 4-Very severe.

All subjects will be evaluated with CCQ (clinical COPD questionnaire). 6 min walk test and BODE index will be assessed.

After measuring the baseline value of the above parameters subjects will be divided into two groups randomly (group A & B). All the subjects of the both groups will receive standard inhalational therapy as per the GOLD guidelines. Group B subjects will additionally receive yoga therapy. Subjects will be followed up at monthly intervals for 6 months. Subject will report if exacerbations occurs which is define as per GOLD criteria. The number of exacerbations will be recorded. All subjects will be assessed at each visit with the CCQ (Clinical COPD questionnaire). Subjects will fill CCQ at weekly intervals for prompt identification of exacerbations and this will be reviewed at each visit.

EXIT FROM THE STUDY
1. Patients request
2. Non compliance with study protocol.

a. Ethical clearance and informed consent

The study protocol was passed by TNPESU Institutional Ethical Committee. All procedures were performed according to the Declaration of Helsinki research ethics. Each participant received detailed information about the study and provided written informed consent before the trial commenced.

3. EXPERIMENTAL DESIGN

<table>
<thead>
<tr>
<th></th>
<th>Yoga group (n=30)</th>
<th>Medicinal group (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients screened</td>
<td>(n=100)</td>
<td></td>
</tr>
<tr>
<td>Underwent clinical</td>
<td></td>
<td></td>
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<tr>
<td>examination (n=100)</td>
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<td></td>
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<tr>
<td>Random assignment</td>
<td></td>
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<tr>
<td>(n=60)</td>
<td></td>
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<tr>
<td>Dropouts (n=0)</td>
<td></td>
<td>Dropouts (n=0)</td>
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<tr>
<td>Final analysis (n=30)</td>
<td></td>
<td>Final analysis (n=30)</td>
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<td>Final analysis (n=30)</td>
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<td>Final analysis (n=30)</td>
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</tbody>
</table>

Fig.1 Participant’s flowchart
4. The experimental design used for this study was pre and post test random group design involving sixty subjects, who were divided at random into two groups of thirty each. This study consisted of two experimental groups. Group I underwent medicinal management and Group II underwent medicinal management and yogic practice. All the subjects were tested prior to and after the yoga training on selected variables.

a. Intervention

Included a combination of asanas, loosen exercises, breathing exercises, pranayama, meditation, and yogic counseling and lectures (Table 1).

### DESCRIPTION OF YOGA PRACTICE

### TABLE IV LIST OF ASANAS

<table>
<thead>
<tr>
<th>POSITION</th>
<th>NAME OF THE YOGIC PRACTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shatkarma</td>
<td>Jalneti, Kapalbhati</td>
</tr>
<tr>
<td>Suryanamaskar</td>
<td>Suryanamaskar</td>
</tr>
<tr>
<td>Standing</td>
<td>Tadasana, Ardhachakrasana, katichakrasana</td>
</tr>
<tr>
<td>Supine</td>
<td>savasana, pawanmuktasana</td>
</tr>
<tr>
<td>Prone</td>
<td>bhujangasana, salabhasana</td>
</tr>
<tr>
<td>Kneeling</td>
<td>vajrasana, uttanmandukasana</td>
</tr>
<tr>
<td>Long Sitting</td>
<td>gomukhasana, vakrasana</td>
</tr>
<tr>
<td>pranayama</td>
<td>Nadishodhan, bhastrika</td>
</tr>
<tr>
<td>Meditation</td>
<td>om chanting</td>
</tr>
</tbody>
</table>

Waitlist controls were offered the 12 weeks yoga program after the intervention period and post-testing were complete.

b. Assessments

Six minutewalk distance (6MWD), PFT, COPD questionnaire and CRP were measured...
in both groups pre- and post-intervention.

c. **Six minute walk test**

This was performed according to the American Thoracic Society guidelines [53]. As an objective measurement of true functional capacity, the 6MWT is usually better than self-reports or questionnaires to overcome over- or under-estimation. For patients with COPD it is a good indicator of exercise capacity and also reflects an individual's sub maximal level of functional capacity to perform activities of daily living.

Participants were asked to walk back and forth at their own pace in a flat, straight, hard surfaced 35 m corridor, and to try and cover as much distance as possible in the time allotted. Rest stops were permitted during the test, but they were instructed to resume walking as soon as possible. Standardized phrases were used at each minute (e.g., “You are doing fine. Five minutes to go,” “Keep up the rhythm. Four minutes to go,” “You are doing fine. You are halfway to the end,” “Keep up the rhythm. Only 2 min to go,” “You are doing fine. Only 1 min to go”). Total distance covered was recorded.

*PFT*

6. A person blowing into a spirometer. Smaller handheld devices are available for office use.
7. The diagnosis of COPD should be considered in anyone over the age of 35 to 40 who has shortness of breath, a chronic cough, sputum production, or frequent winter colds and a history of exposure to risk factors for the disease. Spirometry is then used to confirm the diagnosis. Screening those without symptoms is not recommended.

9. **Spirometry**

10. Spirometry measures the amount of airflow obstruction present and is generally carried out after the use of a bronchodilator, a medication to open up the airways. Two main components are measured to make the diagnosis: the forced expiratory volume in one second (FEV₁), which is the greatest volume of air that can be breathed out in the first second of a breath, and the forced vital capacity (FVC), which is the greatest volume of air that can be breathed out in a single large
breath. Normally, 75–80% of the FVC comes out in the first second and a FEV₁/FVC ratio of less than 70% in someone with symptoms of COPD defines a person as having the disease. Based on these measurements, spirometry would lead to over-diagnosis of COPD in the elderly. The National Institute for Health and Care Excellence criteria additionally require a FEV₁ of less than 80% of predicted.

11. Evidence for using spirometry among those without symptoms in an effort to diagnose the condition earlier is of uncertain effect and is therefore currently not recommended. A peak expiratory flow (the maximum speed of expiration), commonly used in asthma, is not sufficient for the diagnosis of COPD.

12. Severity

<table>
<thead>
<tr>
<th>MRC shortness of breath scale</th>
</tr>
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<tbody>
<tr>
<td>Grade</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
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<tr>
<td>5</td>
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</table>

13. GOLD grade

<table>
<thead>
<tr>
<th>Severity</th>
<th>FEV₁ % predicted</th>
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</thead>
<tbody>
<tr>
<td>Mild (GOLD 1)</td>
<td>≥80</td>
</tr>
<tr>
<td>Moderate (GOLD 2)</td>
<td>50–79</td>
</tr>
<tr>
<td>Severe (GOLD 3)</td>
<td>30–49</td>
</tr>
<tr>
<td>Very severe (GOLD 4)</td>
<td>&lt;30</td>
</tr>
</tbody>
</table>

14. There are a number of methods to determine how much COPD is affecting a given individual. The modified British Medical Research Council questionnaire (mMRC) or the COPD assessment test (CAT) are simple questionnaires that may be used to determine the severity of symptoms. Scores on CAT range from 0–40 with the higher the score, the more severe the disease. Spirometry may help to determine the severity of airflow limitation. This is typically based on the FEV₁ expressed as a percentage of the predicted "normal" for the person's age, gender, height and weight. Both the American and European guidelines recommended partly basing treatment recommendations on the
FEV₁. The GOLD guidelines suggest dividing people into four categories based on symptoms assessment and airflow limitation. Weight loss and muscle weakness, as well as the presence of other diseases, should also be taken into account.

a. **COPD QUESTIONNAIRE**

Participants were asked to rate their degree of symptoms on a vertical modified COPD questionnaire scale labeled 0e10. The scores were noted before and after the intervention.

b. **CRP C- Reactive protein**
CRP is an invasive method affording a rapid measurement of Inflammation in COPD patients.

c. **Data collection**

Demographic and vital clinical data (Table 2) including personal, job, family, and stress history were obtained by semi-structured interviews at the time of enrollment. Participants underwent physical examinations, anthropometric measurements, and assessment of lung function.

**2.14. Statistical analysis**

Statistical analysis was performed using SPSS 18 (IBM Corporation, USA). After ascertaining normality of data, paired t-tests were used to determine the significance of variable differences before and after the intervention. Means of the both groups were compared for all variables using Student's t-test. The level of statistical significance was set at $P < 0.05$ for all tests.

<table>
<thead>
<tr>
<th>variable</th>
<th>Medicinal group</th>
<th>Yoga group</th>
<th>Between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fev1</td>
<td>0.024+0.013</td>
<td>0.078+0.444</td>
<td>-6</td>
</tr>
<tr>
<td>CRP</td>
<td>-1</td>
<td>3.166+0.77</td>
<td>14</td>
</tr>
<tr>
<td>6MWT</td>
<td>9.06+6.99</td>
<td>45.53</td>
<td>-6</td>
</tr>
<tr>
<td>COPD</td>
<td>-2.56+-0.91</td>
<td>-8.13+-3.70</td>
<td>7.85592</td>
</tr>
</tbody>
</table>

***P<0.00001 There result is significant as $p<.05$.***

**3.2 Changes in the variables after yoga intervention**

For the majority of patients, the intensity of dyspnea decreased after the yoga intervention;
they were also able to walk further in the stipulated 6 min time. Similar improvements were also observed between pre- and post-intervention testing in their physiological responses (PFR and CRP).

15. Results
18. 1 demographic data
Of the 60 COPD patients who were recruited, (30 in each group) completed all assessments. Fig. 1
16. The result of the study on COPD related variables, PFT reveals that the experimental group namely yogic practice groups (YPG) had significantly improved after the 12 weeks of training. Besides, the analysis of the data indicated that there was a significant difference between the PEG and YPG on all the selected dependent variables. Moreover, YOGA training showed better results in the entire selected dependent variables than the medicinal group. The present study indicates that 12 weeks of yogic practice improve the respiratory fitness level among the COPD patients. The above findings very well be supported by observations made by the following studies conducted.

17. RESULTS:
USED ASSUMPTION-the base population of both medicinal management group and yoga population is same.

1. P value <0.05 for all therefore its statistically significant.
2. We reject the null hypothesis that mean value of yoga and other is same. In fact yoga mean is higher than others.

CONCLUSIONS
In the present investigation, as a result of Yoga training programmes the following improvements occurred on COPD related variables, PFT, and COPD questionnaires of COPD patients.

1. It was concluded from the results of the study that the yoga practices groups showed significant improvement in CRP, PFT, Six minute walk test and COPD questionnaires when compared with a medicinal group as well as pre test.
2. Regular practice of yoga- significantly reduced the level of CRP and prevents acute exacerbations.
3. 12 weeks of yoga practices significantly reduced the high CRP level.
4. Systematic and well planned yoga practice programs significantly improves PFT values in COPD patients.
5. Due to the influence of yoga practices significantly increased the level of distance covered in six minute walk test when compared with a medicinal group as well as pre test.
6. The yoga training has differed significantly in all the dependent variables when compared to the medicinal group.

7. YOGA training is a suitable training system to improve the COPD related fitness parameters, PFT and improve the CPR level in blood among the COPD patients.

The current limited evidence suggested that yoga training has a positive effect on improving lung function and exercise capacity and could be used as an adjunct pulmonary rehabilitation program in COPD patients. However, further studies are needed to substantiate our preliminary findings and to investigate the long-term effects of yoga training.

**Keywords:** Chronic obstructive pulmonary disease (COPD), yoga, pulmonary function, meta-analysis

18.

The study's promising results, reducing dyspnea and fatigue, and improving functional exercise capacity in COPD patients, indicate the value of using yoga in programs of pulmonary rehabilitation as an adjunct to conventional care. More rigorously designed, larger scale research with longer follow-up should be conducted, particularly as that would also expand yoga's evidence base.

**ACKNOWLEDGMENT**

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